

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
OFFICE OF COMPLIANCE

**FIFRA / TSCA**  
**GOOD LABORATORY PRACTICE INSPECTION REPORT**

LABORATORY:	Charles River Laboratories, Inc. 640 N. Elizabeth Street Spencerville, OH 45887
CONTACT PERSON:	Mr. Rusty Rush Site Director Phone: (419) 647-8468 Rusty.rush@crl.com
DATES OF INSPECTION:	September 25 - 26, 2018
INVESTIGATION ID:	20184079754
INSPECTOR/AUDITOR:	Daniel Myers EPA, Office of Compliance, GLP Program Denver, Colorado Phone: 303-462-9392 Myers.dan@epa.gov
SCOPE OF INSPECTION	Determine compliance with 40 CFR 160 and 40 CFR 169.2(k) for FIFRA and 40 CFR 792 for TSCA

Good Laboratory Practice Program  
Denver, Colorado

## SUMMARY

A U.S. Environmental Protection Agency (EPA) Federal Insecticide, Fungicide, Rodenticide, Act (FIFRA) and Toxic Substances Control Act (TSCA) Good Laboratory Practice (GLP) inspection was conducted to compliance with 40 CFR 160, 40 CFR 169.2(k) and 40 CFR 792. One study audit was conducted by the inspector. In addition, a GLP compliance inspection was conducted to determine the laboratories current adherence to the TSCA GLP regulations. Findings from the FIFRA / TSCA GLP inspection and study audits are summarized below.

- No observed adverse findings.

### I. INTRODUCTION

A Neutral Scheme FIFRA / TSCA GLP inspection was conducted at Charles River Laboratories in Spencerville, OH, on September 25 - 26, 2018 to determine compliance with 40 CFR 160, 169.2(k) and 40 CFR 792. The inspector assigned was Mr. Daniel Myers. Information for this research facility's capabilities can be found at [www.criver.com](http://www.criver.com)

### II. OPENING CONFERENCE

An opening conference was held beginning at approximately 9:00 a.m. on September 25, 2018. The inspection was led by Mr. Daniel Myers, Chemist, from EPA's GLP Program.


Official credentials were presented to facility officials upon entry. Notice of Inspections [Exhibit I] for both FIFRA and TSCA were presented to and signed by Mr. Rush.

### III. NARRATIVE

The following GLP compliance inspection and study audit were accomplished during the inspection.

#### TSCA GLP Compliance Inspection:

The GLP standards compliance inspection was conducted through interviews with facility personnel and tours of laboratory, archives and test substance / system storage areas. Personnel *curricula vitae* and training records were reviewed, as well as SOPs and equipment calibration/maintenance logs. The following on-going study was used to provide a basis to conduct the GLP compliance inspection:

- "A 90-day Study of  by Dietary Administration in Rats" (Compliance Inspector: Daniel Myers)
  - No observed adverse findings were noted during the Compliance Inspection

**FIFRA GLP Study Audit:**

This study audit was accomplished through review of available raw data, records, reports, interviews with study personnel and review of laboratory operations. The audit was based on: completeness of raw data, conformance of raw data to study report findings and conclusions, adherence to GLP Standard requirements, appropriate SOPs, and the study protocol.

The following aspects of the studies were reviewed: protocol, raw data, final study report, record keeping, test system records, equipment records, quality assurance, test substance receipt, distribution and administration, and chemical characterization.

The following describe any observations made, and activities undertaken during the facility inspection and audit of the studies with respect to the U.S. EPA FIFRA GLP regulations under 40 CFR §160 and 169.2(k):

- No observed adverse findings were noted during the audit of these studies. -

1) **Pyridine**: Acute Single-Dose Oral Gavage Neurotoxicity Screening Study in Rats

Lab Proj. No.: 20097188

MRID: 50164504

Note: For this study the original report submitted to the EPA contained a GLP compliance statement signed by the study director only. This is not compliant with the FIFRA GLP regulation 40 CFR 160.12 which requires signatures of the applicant, sponsor and the study director. As a result of this inspection / audit, Charles River submitted a report amendment which includes the appropriate signatures. This amendment is included in Exhibit 4.

IV. **EXIT DISCUSSION**

The exit conference was held Wednesday, September 26, 2018 by Daniel Myers to review findings and recommendations of the FIFRA and TSCA GLP standards inspection and data audit. Inspection Observations form [Exhibit 2] was completed and copied for the facility providing written indication of the inspector's observations discussed during the inspection and closing conference. Both a FIFRA and a TSCA Receipt for Samples form [Exhibit 3] was provided to the facility for documents obtained during the inspection.

V. EXHIBITS

Exhibit 1	FIFRA and TSCA <u>Notice of Inspection(s)</u>	(2 pages)
Exhibit 2	<u>Inspection Observations form</u>	(1 page)
Exhibit 3	FIFRA and TSCA <u>Receipt for Samples</u> forms	(2 pages)
Exhibit 4	Final Report Amendment No. 2	(9 pages)

VI. SIGNATURE:

Inspector/Auditor:    Name:       Daniel Myers  
                                  Affiliation:    U.S. EPA/OECA/OC/GLP Program

**DANIEL MYERS**    Digitally signed by DANIEL MYERS  
 Date: 2018.11.20 15:04:36 -07'00'

Daniel Myers

**MARK LEHR**    Digitally signed by MARK LEHR  
 Date: 2019.03.26 13:32:16 -06'00'

Admin./ Technical Review

**FRANCISCA LIEM**    Digitally signed by FRANCISCA LIEM  
 Date: 2019.04.09 13:00:49 -04'00'

Approver